Module F

Principles of Disinfection and Sterilization in the outpatient setting

Objectives

- State the principles of disinfection and sterilization
- List the current methods for disinfection and sterilization per CDC guideline recommendations

Order of resistance of microorganisms to disinfectants

Hardest to Kill

Prions (Creutzfeldt-Jakob Disease (CJD), mad cow disease)
Spores (*C. difficile)*
Mycobacteria (Tb)
Non-enveloped viruses (norovirus)
Fungi (*Candida)*
Vegetative bacteria (MRSA, VRE)
Enveloped viruses (HIV, HBV)

Easiest to Kill

Where are you processing your instruments?

Management of contaminated items

- Contaminated reusable items should be handled as little as possible
- When handling contaminated items appropriate PPE should be used
- Gross soil or debris should be removed at the point of use (gauze sponge moistened with water/disinfectant wipe for example)
- Soiled items should be immediately contained and transported to the decontamination area or soiled utility room where cleaning procedures can be accomplished away from patient care

Transport of contaminated items

- Contaminated items must be contained during transport. The type of container depends on the item being transported:
  - Puncture-resistant, leak-proof, closable containers must be used for devices with edges or points capable of penetrating container or skin
  - All containers must have a bio-hazard label or be red in color
  - Contaminated items should never be transported via gloved hands alone.
- Items should be kept moist during transport by adding a towel moistened with water (not saline) or a foam, spray or gel product specifically intended for this use
- Avoid transporting contaminated items in a liquid
- Reusable collection containers for holding contaminated items should be made of material that can be effectively decontaminated
- Use separate collection containers for contaminated versus re-processed or clean items

Factors influencing the efficacy of disinfection and sterilization processes

- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration and exposure time to the disinfectant/sterilant
- Nature of the object
- Temperature, pH, and water hardness

Cleaning instruments manual

- Soak in enzymatic or non-enzymatic detergent
- Wear the appropriate PPE
- Keep instruments submerged in solution and scrub with brush
- Thoroughly rinse the instrument
- Allow instrument to dry

Cleaning instruments automated

- Types:
  - Ultrasonic cleaner
  - Instrument washer
  - FDA regulated instrument washer (household dishwasher NOT recommended)
- Benefits:
  - Improved efficacy
  - Reduced employee exposure to splash and sharps

Fig. 2 Cleaning in an instrument washer (right) and an ultrasonic cleaner should be performed according to the manufacturer's directions.

Spaulding Classification

Spaulding Classification of Surfaces:

1. **Critical** – Objects which enter normally sterile tissue or the vascular system and require sterilization
2. **semi-critical** – Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores
3. **non-critical** – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

Processing Critical Instruments

Processing Critical Instruments

- Penetrate or enter normally sterile tissue or spaces, including the vascular system
  - Surgical instruments, cardiac catheters, IV devices, urinary catheters
- Must be sterilized between uses or used as single-use disposable devices
- Goal: Sterility = devoid of all microbial life

Sterilization

The complete elimination or destruction of all forms of microbial life by either physical or chemical processes.

Methods of sterilization

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone
Vaporized hydrogen peroxide
Steam formaldehyde

Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Rapid cycle time
  - Least affected by organic/inorganic soils
  - Penetrates medical packing, device lumens

Steam Sterilization

- Disadvantages
  - Deleterious for heat labile instruments
  - Inappropriate for heat-sensitive instruments
  - Inappropriate for moisture-sensitive instruments
    - Dulling
    - Rusting
  - Potential for burns

Steam Sterilization

- Steam under pressure (autoclaving)
  - Gravity displacement
  - Pre-vacuum

Process times for packaged items

Method	Exposure (minutes)	Temperature Range	Dry Time (minutes)
Steam autoclave			Depends on the item being sterilized
●Gravity	30	121°C	
●Prevacuum	4	132°C	

Dry Heat Sterilization

- Transfers heat energy from air inside the oven to the instruments
- Requires higher temperatures
- Good for items that are likely to dull or rust in the autoclave,
- Good for powders, cellulose and ink
- Packaging must be able to withstand high temperatures

Recommendations Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat

Conclusions . . .

- All sterilization processes effective in killing spores.
- Cleaning removes salts and proteins and MUST precede sterilization.
- Failure to clean or ensure exposure of microorganisms to sterilant could interfere with the sterilization process.

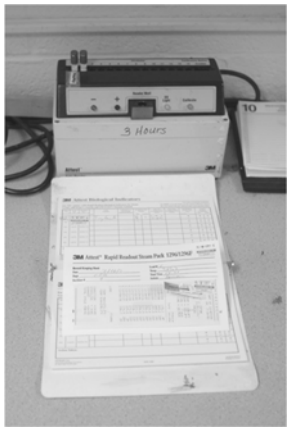
Packaging

- Peel packs
- Rigid containers
- Self seal roll stock
- Sterile wraps woven and non-woven
- Must be FDA approved

Loading

- Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant
- Peel packs and non-perforated containers should be placed on their edge

Monitoring



Sterilization Monitoring

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

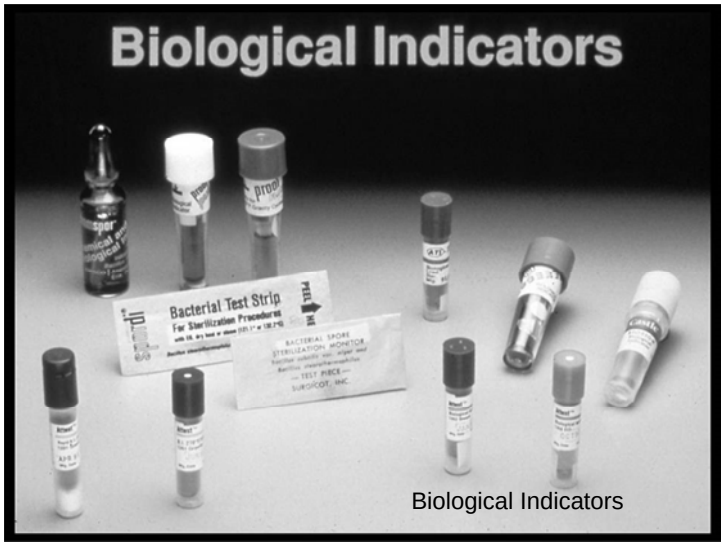
- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters reached
- Biological - *Bacillus* spores that directly measure sterilization

Monitoring of Sterilizers

- Internal Chemical Indicator
  - Validates the sterilant penetrated the pack or tray
  - Advantage of the pack control monitor is that it is inside each pack in multiple locations
  - Detect local problem

Biological Monitors

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- Ethylene oxide (ETO) - *B. atrophaeus*



Biological Indicators

Recommendations Monitoring of Sterilizers

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

Recommendations Monitoring of Sterilizers

Following a single positive biological indicator from steam sterilization:

- Remove the sterilizer from service and review sterilizer instructions
- Retest the sterilizer
- If spore test negative, put the sterilizer back in service
- If the spore test is positive: do not use until it has been inspected; and recall (to the extent possible) all items processed since the last negative spore test; challenge in three consecutive empty sterilization cycles.
- Single positive biological indicator (BI) from other than steam sterilization: treat as non-sterile all items back to last load tested with negative indicator

Record-Keeping

Maintain sterilization records (physical, chemical and biological)
For each sterilization cycle record"

- the type of sterilizer and cycle used;
- the load identification number;
- the load contents,
- the exposure parameters (time and temperature);
- the operator's name or initials; and
- the results of physical, chemical, and biological monitoring.

Summary
Sterilization Recommendations . . .

- Steam is preferred for critical (and semi-critical) items not damaged by heat
- Always follow manufacturer's operating instructions
- Use an "FDA cleared" container, wrapping or packaging system that is compatible with the type of sterilization process used
- Do not overload the chamber

Recommendations
Storage of Sterile Items

- Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised.
- Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and if applicable the expiration date.

Recommendations
Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g. moisture).
- Packages should be evaluated before use for loss of integrity. Repack and reprocess if compromised.
- If time related storage of sterile items is used, label the pack at the time of sterilization with an expiration date. Once this date expires, reprocess the pack.

Storage in healthcare facilities
General guidelines

- All patient care items must be stored at least 8" off the floor
- Open rack storage should have a bottom shelf (plexi-glass for example)
- Stored at least 18" below the ceiling or the sprinkler head (according to fire code)
- Stored at least 2" inches from outside wall
- Items should be stored in areas of limited traffic
- Stored in an area with controlled temperature and humidity
- Outside shipping containers and corrugated cartons should not be used as storage containers
- Items should not be stored under sinks or exposed water/sewer pipes
- Windowsills should be avoided
- Closed or covered cabinets are preferred

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Semi-Critical objects contact <u>mucous membranes or non-intact skin</u> and require high level disinfection

Goal:
High-level disinfection = free of <u>all</u> microorganisms except high numbers of bacterial spores

High-Level Disinfectants

Germicide	Concentration
Glutaraldhyde (Cidex)	≥ 2.0%
Ortho-phthaladehyde (Cidex OPA)	0.55%
Hydrogen Peroxide* (Sporox)	7.5%
Hydrogen Peroxide and peracetic acid* (Peract)	1.0% / 0.08%
Hydrogen Peroxide and peracetic acid* (Endospore +)	7.5% / 0.23%
Hypochlorite (free chlorine)* (Sterilox ©)	650-675 ppm
Accelerated hydrogen peroxide (Resert XL)	2.0%
Peracetic Acid (Steris 20)	0.2%
Glutaraldehyde and Isopropanol (Aldahol III)	3.4% / 26%
Glutaraldehyde and phenol/phenate (Sporicidin)	1.21% / 1.93%

Exposure time ≥8 -45 min (US) and temperature 20-25°C;
*May cause cosmetic and functional damage

Semi-critical instruments

- Examples of semi-critical devices
  - Endocavitary probes
  - Tonometers
  - Diaphragm fitting rings
  - Vaginal speculums
  - Endoscopes
  - Respiratory therapy equipment
  - Anesthesia equipment

Processing Semi-critical instruments

Methods for processing:

The most common used in outpatient facilities is immersion in either Glutaraldehyde (Cidex®) or Ortho-phthaladehyde (Cidex OPA®)

Manufacturer's instructions for dilution and quality control testing must be followed:

- Submerge the test strip into the solution prior to each use to monitor minimum effective concentration (MEC)
- Remove excess by standing upright on paper towel
- Read results according to manufacturer's instructions *(recommended time period and change in color of the test strip)*
- Document findings

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Non-Critical objects contact intact skin but not mucus membranes and require low level disinfection

Liquid Disinfectants

Disinfectant Agent	Use Concentration
Ethyl or isopropyl alcohol	70% - 90%
Chlorine (bleach)	100 ppm
Phenolic	UD
Iodophor	UD
Quaternary ammonium compound (QUAT)	UD
Improved/Accelerated hydrogen peroxide	0.5%, 1.4%

UD = Manufacturer's recommended use dilution

Cleaning Recommendations

Clean and disinfect surfaces using correct technique

- Clean to dirty
- Prevent contamination of solutions
  - Don't use dried out wipes
- Physical removal of soil (elbow grease)
- Contact time
- Monitor the cleaning/disinfection process

Other Environmental Issues

Blood and Body Fluid Spills

- Promptly clean and decontaminate
- Use appropriate PPE
- Clean spills with dilute bleach solution (1:10 or 1:100) or an EPA-registered hospital disinfectant with a TB or HIV/HBV kill claim.

Knowledge check

- Patient care equipment and devices should be disinfected/sterilized based on:

1. Items intended use
2. What the item is going to be in contact with, for example, mucus membranes or non-intact skin
3. The number of patients you have scheduled for the day
4. What the physician tells you to do
   1. 1 and 2
   2. 1 and 3
   3. All of the above

Recommendations Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency:
  - Staff receive hands-on training
  - Work with supervision until competency is documented
  - Competency testing should be conducted at commencement of employment and no less than annually
  - Training and competencies should be documented

Recommendations for Quality Control

- Conduct infection control rounds no less than annually and more often if high risk area (GI clinic, Urology, Endoscopy)
- Ensure all products used for disinfection and/or sterilization have been approved by infection prevention
- Follow manufacturer instructions for use (IFUs)for preparation and packing of items

Resources

Questions?